Queensland Health

Factsheet – Research and analytical laboratories using scheduled substances

Who is this factsheet for?

This factsheet is for persons who hold a general approval to use regulated poisons for non-therapeutic purposes for research or analytical purposes in a non-university laboratory setting under the Health (Drugs and Poisons) Regulation 1996 (HDPR) and who intend to continue to hold an approval under the *Medicines and Poisons Act 2019* (the MPA) which replaced the HDPR on 27 September 2021.

This factsheet may also be used by persons seeking to apply for a general approval to use regulated poisons for non-therapeutic purposes for research or analytical purposes in a non-university laboratory setting.

How will it affect me?

- Regulated poisons include S2, S3, S4, S7 and S8 poisons when not used or intended to be used for therapeutic purposes and prohibited substances (S9 and S10 substances).
- A general approval is required to deal (buy, possess, use and dispose) with regulated poisons, other than non-restricted S7 poisons, for non-therapeutic purposes. Restricted S7 (RS7) poisons are prescribed in schedule 1 of the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 (the Poisons Regulation).
- S8, S9 and S10 substances used for non-therapeutic purposes are classed as high-risk poisons. Users of high-risk poisons will be required to keep a high-risk poison register to record all dealings with theses poisons from purchase to disposal.
- There are no fees associated with obtaining a general approval.
- Authorisations under the HDPR will transition as closely as possible to a new authority under the MPA. The authority holder may apply for an amendment to their authority to add additional substances.

Exemptions for reference materials

- Under the Poisons Regulation the analytical reference materials are exempt from requiring an authority due to the low risk associated with their use.
- Persons using reference materials in analytical laboratories may purchase and use reference materials containing up to 1 g of regulated poisons without an approval. The reference materials must be manufactured by an accredited laboratory as specified in section 13 of the Poisons Regulation.

Substance management plans

- A general approval holder who operates at multiple sites, or who deals with high-risk poisons, will require a Substance Management Plan (SMP). An SMP is a document that identifies and addresses the risks associated with carrying out regulated activities.
- The SMP must comply with the Departmental Standard '*Substance management plans for regulated poisons – version 1.' Substance Management Plan Checklist – research, analysis & teaching'* is available to assist the development of an SMP.
- General approval holders will be given until 26 September 2022 to prepare and implement SMPs.

Storage, registers and recordkeeping

- The Poisons Regulation requires the general approval holder to implement measures to ensure that the purchase, possession, application (use), transport and disposal of regulated poisons are undertaken in a safe and secure manner.
- Storage and transport of regulated poisons must be undertaken in a manner which ensures that access is restricted to persons authorised by the authority holder.
- The Poisons Regulation requires authority holders for high risk poisons to implement measures to ensure the purchase, storage and transport of such poisons is undertaken in a safe and secure manner and is restricted to persons authorised under the SMP. Additional physical or electronic security measures are also required for high-risk poisons.
- The High-Risk Poison Register may be electronic or paper based and must include details such as date, name, form, strength and amount of poison, nature of dealing etc. to be able to reconcile the amount of poison received, applied, supplied or disposed of.
- The Poisons Regulation requires that waste from high risk poison is destroyed under the supervision of an inspector under the MPA or another person authorised by the Chief Executive.
- Regulated poisons must be disposed of in a way that is lawful under the *Environmental Protection Act 1994* or by giving the waste to a person authorised under a substance authority to dispose of it.
- Any RS7 and high-risk poison losses or releases causing or likely to cause a person to require medical attention must be reported to the chief executive as soon as possible, but within seven days.
- Wholesale buyers of regulated poisons must give a purchase order to the supplier, including information demonstrating authority to possess the poison. Purchase orders must meet specific verification and security criteria and buyers of high-risk poisons must notify the supplier when they have received the poison.
- Records such as purchase orders, invoices, disposal of high-risk poisons must be kept for five years.

How to apply for a licence

To apply for a general approval, go to '[Poisons general approval forms]'.

For further information

- Relevant factsheets and checklist
  - Poisons terms
  - Transitional arrangements
  - Substance Management Plan Checklist – research, analysis & teaching
- Departmental Standard
  - Substance management plans for regulated poisons – version 1